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TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371				U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR N/A 10/049655	
INTERNATIONAL APPLICATION NO. PCT/US00/20938		INTERNATIONAL FILING DATE 31 July 2000		PRIORITY DATE CLAIMED 5 August 1999	
TITLE OF INVENTION Medication Delivery Pen					
APPLICANT(S) FOR DO/EO/US Becton, Dickinson and Company					
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:					
<ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. 2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below. 4. <input type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (Article 31). 5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c) (2)) <ol style="list-style-type: none"> a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)) <ol style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)). 11. <input type="checkbox"/> A copy of the International Preliminary Examination Report (PCT/IPEA/409). 12. <input checked="" type="checkbox"/> A copy of the International Search Report (PCT/ISA/210). 					
Items 13 to 20 below concern document(s) or information included:					
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Petition for Revival of an International Application for Patent Designating the U.S. - Abandoned Unintentionally under 37 CFR 1.137 (b)					

PTO/PST Rec'd 13 FEB 2002

UNITED STATES PATENT APPLICATION**FOR: MEDICATION DELIVERY PEN**

5

BACKGROUND OF THE INVENTION**1. FIELD OF THE INVENTION**

10 The present invention relates to a medication delivery pen having a variety of features and, more particularly, a medication delivery pen having a spring biased leadscrew to make priming easier and minimize underdosing and a magnifier for setting the dose.

15

2. DESCRIPTION OF RELATED ART

Hypodermic syringes are used to deliver selected doses of medication to patients. The prior art hypodermic syringe includes a syringe barrel having opposed proximal and distal ends. A cylindrical chamber wall extends between the ends and defines a fluid
20 receiving chamber. The proximal end of the prior art syringe barrel is substantially open and receives a plunger in sliding fluid tight engagement. The distal end of the prior art syringe barrel includes a passage communicating with the chamber. A needle cannula may be mounted to the distal end of the prior art syringe barrel, such that the lumen of the needle cannula communicates with the passage and the chamber of the syringe barrel.
25 Movement of the plunger in a proximal direction draws fluid through the lumen of the needle cannula and into the chamber. Movement of the plunger in a proximal-to-distal direction urges fluid from the chamber and through the lumen of the needle cannula.

Medication to be injected with the prior art hypodermic syringe often is stored in a vial having a pierceable elastomeric seal. Medication in the prior art vial is accessed by piercing the elastomeric seal with the needle cannula. A selected dose of the medication may be drawn into the chamber of the syringe barrel by moving the plunger a selected distance in a proximal direction. The needle cannula may be withdrawn from the vial, and the medication may be injected into a patient by moving the plunger in a distal direction.

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the course of the day. The required dose of insulin will vary from patient to patient, and for each patient may vary during the course of the day and from day to day. Each diabetes patient will establish a regimen that is appropriate for his or her own medical condition and for his or her lifestyle. The regimen typically includes some combination of a slow or medium acting insulin and a faster acting insulin. Each of these regimens may require the diabetes patient to periodically self-administer insulin in public locations, such as places of employment or restaurants. The required manipulation of the standard prior art hypodermic syringe and vial can be inconvenient and embarrassing in these public environments.

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Medication delivery pens have been developed to facilitate the self-administration of medication. One prior art medication delivery pen includes a cartridge holder into which a cartridge of insulin or other medication may be received. The cartridge holder is an elongate generally tubular structure with proximal and distal ends. The distal end of the prior art cartridge holder includes mounting means for engaging a double-ended needle cannula. The proximal end also includes mounting means for engaging a driver and dose setting apparatus as explained further below. A disposable cartridge for use

with the prior art cartridge holder includes a distal end having a pierceable elastomeric seal that can be pierced by one end of a double-ended needle cannula. The proximal end of this prior art cartridge includes a plunger slidably disposed in fluid tight engagement with the cylindrical wall of the cartridge. This prior art medication delivery pen is used
5 by inserting the cartridge of medication into the cartridge holder. A prior art pen body then is connected to the proximal end of the cartridge holder. The pen body includes a dose setting apparatus for designating a dose of medication to be delivered by the pen and a driving apparatus for urging the plunger of the cartridge distally for a distance corresponding to the selected dose.

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The user of the pen mounts a prior art double-ended needle cannula to the distal end of the cartridge holder such that the proximal point of the needle cannula pierces the elastomeric seal on the cartridge. The patient then selects a dose and operates the pen to urge the plunger distally to deliver the selected dose. The dose selecting apparatus
15 returns to zero upon injection of the selected dose with this prior art medication delivery pen. The patient then removes and discards the needle cannula, and keeps the prior art medication delivery pen in a convenient location for the next required medication administration. The medication in the cartridge will become exhausted after several such administrations of medication. The patient then separates the cartridge holder from the
20 pen body. The empty cartridge may then be removed and discarded. A new cartridge can be inserted into the cartridge holder, and the cartridge holder and pen body can be reassembled and used as explained above.

The above described medication delivery pen is effective and much more
25 convenient for self-administration of medication than the hypodermic syringes that use separate medication cartridges. However, the above-described medication delivery pen requires a number of parts which make the manufacture of these pens very expensive.

Hence, it is necessary to provide a medication delivery pen having a simple mechanism for setting the desired dose, simplifies loading of the cartridge, and makes priming easier to minimize underdosing.

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SUMMARY OF THE INVENTION

The present invention relates to a medication delivery pen that addresses the above-identified problems and provides numerous features that have become expected by medication delivery pen users.

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The medication delivery pen according to the present invention includes a mechanism that automatically disengages the drive mechanism from the dose control mechanism to permit the user to reset the dose on the medication delivery pen.

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Another feature of the present invention is an automatic mechanism that allows the user to easily load a new cartridge and automatically repositions the leadscrew next to the plunger when the cartridge holder is mounted on the body of the medication delivery pen.

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Another feature of the present invention is a magnifier for easy viewing and setting of the desired dose.

BRIEF DESCRIPTION OF THE DRAWINGS

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Fig. 1 is an exploded perspective view of a medication delivery pen according to the present invention.

Fig. 2 is a perspective view of the leadscrew in the medication delivery pen shown in Fig. 1.

Fig. 3 is a perspective view of the drive nut shown in Fig. 1.

5 Fig. 4 is a perspective view of the retract nut shown in Fig. 1.

Fig. 5 is a perspective view of the shuttle shown in Fig. 1.

10 Fig. 6 is a cross-sectional view of the body of the medication delivery pen shown in Fig. 1.

Fig. 7 is a perspective view of the dose knob of the medication delivery pen shown in Fig. 1.

15 Fig. 8 is a distal end view of the dose knob of the medication delivery pen shown in Fig. 1.

Fig. 9 is a cross-sectional view of the medication delivery pen shown in Fig. 1 fully assembled and in a dose setting condition.

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Fig. 10 is a cross-sectional view of the medication delivery pen shown in Fig. 9 in a dose set condition.

25 Fig. 11 is a cross-sectional view of the medication delivery pen shown in Fig. 9 in a reset dose condition.

Fig. 12 is an enlarged cross-sectional view of a section of the medication delivery pen shown in Fig. 11.

DETAILED DESCRIPTION OF THE INVENTION

5 A medication delivery pen 10 according to the present invention is shown in Figs. 1-12. Medication delivery pen 10 includes a cap 1 removably attached to a cartridge holder 2 so to cover cartridge holder 2 between uses of medication delivery pen 10. Cartridge holder 2 receives a cartridge 100, shown in Fig. 9, that is commonly used in
10 such medication delivery pens to provide medication and/or insulin for an injection. Medication delivery pen 10 includes a body 5 having a distal end 51 and a proximal end 52, with cartridge holder 2 being attached to distal end 51 of body 5. Medication delivery pen 10 also includes a dose knob 7, a driver 8, a leadscrew 9, a leadscrew spinner 3, a retract nut 4, a shuttle 6, and a push button 71. Each of these elements are more clearly
15 shown in Figs. 2-8 and are more fully described below.

Driver 8 includes a distal end 81 and a proximal end 82, wherein distal end 81 receives drive nut 8A. In addition, driver 8 includes a plurality of ratchet fingers 84 at distal end 81 that engage a ratchet 53, shown in Fig. 6, within body 5 to allow driver 8 to
20 rotate only in one direction with respect to body 5. Drive nut 8A, shown in Fig. 3, includes a set of threads 85 that interface with a matching set of threads 93 on leadscrew 9, shown in Fig. 2. Leadscrew 9 shown in Fig. 2 includes a distal end 91 and a proximal end 92, with proximal end 92 receiving an end cap or co-pilot 9A, shown in Fig. 1, and distal end 91 receiving leadscrew spinner 3 also shown in Fig. 1. Fig. 2 shows a
25 distinctive thread formed by a set of threads 93 on leadscrew 9. Each thread 93 includes distinctive pyramid projection 94 formed by grooves 95 that cut through threads 93 in a longitudinal direction on leadscrew 9.

Fig. 3 shows drive nut 8A which is received in distal end 81 of driver 8. Drive nut 8A is held within distal end 81 of driver 8 by flanges 89 on drive nut 8A. During assembly, drive nut 8A is inserted through distal end 51 of body 5 while driver 8 is inserted through the proximal end 52 of body 5 and snapped together within body 5 to capture a wall 57 within body 5, shown in Fig. 6.

Fig. 4 is a perspective view of retract nut 4 that more clearly shows attachment arms 41 that mate with snap ring 83 on drive nut 8A to rotatably attach retract nut 4. Retract nut 4 also includes an opening 42 therethrough having a plus sign shape that mates with a set of grooves 94 in leadscrew 9, shown in Fig. 2, to prevent leadscrew 9 from rotating with respect to retract nut 4. Retract nut 4 also has a distal toothed surface 45 that mates with teeth 21 on cartridge holder 2 to prevent retract nut 4 and leadscrew 9 from rotating when cartridge holder 2 is mounted on body 5. However, when cartridge holder 2 is not mounted into body 5, retract nut 4 and leadscrew 9 are free to rotate which permits leadscrew 9 to be free to backdrive into body 5 as the user pushes a new cartridge into place. A leadscrew spinner 3 is attached to a distal end 91 of leadscrew 9 and is allowed to spin freely on leadscrew 9, shown in Fig. 2, in relation to a rubber plunger 111 within the cartridge as leadscrew 9 is backdriven into body 5.

Medication delivery pen 10 according to the present invention also includes a spring 99 and a spring cap 98, as shown in Fig. 1. During assembly spring 99 is placed into driver 8 and is held within driver 8 using spring cap 98 that attaches to proximal end 82 of driver 8. Spring 99 is then contained between spring cap 98 and end cap 9A to bias leadscrew in the distal direction to reduce priming of leadscrew 9 with rubber plunger 111 and make priming much easier than conventional pens. End cap or co-pilot 9A aids in guiding spring 99 during backdriving to reduce friction or rotation of spring 99. Spring 99, however, is not used to drive leadscrew 9 during medication injection.

When cartridge holder 2 mates with retract nut 4, leadscrew 9 is locked against rotation which then enables threads 85 within drive nut 8A to drive leadscrew 9 in the distal direction towards and against the rubber plunger 111 within cartridge 100 during a dispensing operation. Snap ring 83 on drive nut 8A also allows retract nut 4 to float
5 captive thereon thus trapping it from spinning down leadscrew 9 when exchanging cartridges, should a user invert medication delivery pen 10 when changing cartridges.

Fig. 5 is a perspective view of shuttle 6 showing a plurality of keyways 63 therein that travel within a respective set of keys 86 on driver 8, shown in Fig. 1. Shuttle 6 also
10 includes a distal end 61 and a proximal end 62, proximal end 62 having a plurality of teeth 65 and a plurality of ratchets 64 extending from teeth 65 towards distal end 61. Ratchets 64 engage with a plurality of ratchet fingers 73 on a distal end 71 of dose knob 7, shown in Fig. 7 and discussed further below.

Fig. 6 is a cross-sectional view of body 5 more clearly showing distal end 51 and proximal end 52 having a set of dose setting threads 54 therein together with a dose viewing window 55 that receives a magnifier 59 used to magnify the dosage numerals 74 on dose knob 7. Another set of threads 56 located within distal end 51 are used to attach
15 cartridge holder 2 in this embodiment. Of course, other means for attaching cartridge holder 2 to body 5 could also be used and fall within the scope of the present invention as
20 long as sufficient force is applied to retract nut 4 to prevent rotation of retract nut 4 and leadscrew 9 within body 5 when cartridge holder 2 is attached to body 5.

Fig. 9 is a cross sectional view of medication delivery pen 10 shown in Fig. 1
25 fully assembled and in a dose setting condition or a condition for transportability. In Fig. 9 shuttle 6 is fully received within dose knob 7 such that teeth 65 on proximal end 62 of

shuttle 6 are engaged with teeth 78, shown in Fig. 8, within dose knob 7. This causes shuttle 6 and dose knob 7 to rotate together during dose delivery.

Fig. 7 is a perspective view of dose knob 7 having a distal end 71 and a proximal end 72, with a textured section 76 near proximal end 72 to aide the user in turning dose knob 7 to set a desired dose when using medication delivery pen 10. Distal end 71 includes the plurality of ratchet fingers 73 that engage ratchet 64 on shuttle 6 when setting a dose, as shown in Fig. 10, until medication delivery pen 10 is in a reset condition, as shown in Fig. 11. When medication delivery pen 10 is in the reset condition, shuttle 6 has disengaged from dose knob 7 as clearly seen in Figs. 11 and 12. Alternatively, as shown in Fig. 10 during a dose setting condition, shuttle 6 is within dose knob 7 such that ratchet 64 is engaged with ratchet fingers 73. When a user is turning dose knob 7, shuttle 6 slides along driver 8 towards proximal end 52 of body 5 and dose knob 7 rotates around shuttle 6 causing ratchet fingers 73 on dose knob 7 to engage and disengage with ratchet 64 on shuttle 6 to provide an audible and tactile signal during dose setting. As shuttle 6 slides along driver 8, keyways 63 within shuttle 6 interact with keys 86 on driver 8. After a desired dose has been set by the user using dose knob 7, movement of dose knob 7 in a distal direction will cause shuttle 6 to rotate due to the interaction between teeth 65 on proximal end 62 of shuttle 6 and teeth 78 within dose knob 7. As shuttle 6 rotates, keyways 63 within shuttle 6 interact with keys 86 on driver 8 to rotate drive nut 8A about leadscrew 9 and move leadscrew 9 in a distal direction to dispense medication from cartridge 100.

The user sets a desired dose by rotating dose knob 7 in a clockwise direction until the desired dose is displayed through magnifier 59 in body 5. Dose knob 7 includes a plurality of dosage numerals 74 that show through window 55 and an indicator 75, i.e., ▲, that identifies a "reset condition" for medication delivery pen 10. When the desired

dose is reached, the user depresses a push button 71 attached to proximal end 72 of dose knob 7 until dose knob 7 has fully returned within body 5 to the dose setting position shown in Fig. 9.

5 A significant function of the drive mechanism within medication delivery pen 10 is that if the user overshoots the desired dose, medication delivery pen 10 can be reset so that the user may redial for the desired dose. This is accomplished by rotating dose knob 7 completely past the maximum value (30 or 60) until indicator 75 on dose knob 7 is displayed in through magnifier 59 within body 5. This disengages ratchet fingers 73
10 within dose knob 7 from ratchet 64 on shuttle 6 by forcing them apart and releasing shuttle 6 from within dose knob 7. This action is caused by proximal end 62 engaging with a set of stops 87, shown in Fig. 1, on driver 8. Dose knob 7 is then free to rotate back to an initial dose position ("0") upon which ratchet fingers 73 are forced to reengage with ratchet 64 on shuttle 6. Disengaging and re-engaging ratchet 64 and ratchet fingers
15 73 requires significant tactile manipulation and results in an audible click which alerts the user that the resetting function has been performed. After performing the resetting function, ratchet 64 and ratchet fingers 73 are no longer engaged so that no audible or tactile feedback is generated during rotation of dose knob 7 until reset function is completed.

20

While the present invention has been described with respect to a preferred embodiment, it is apparent that various changes can be made without departing from the scope of the invention as defined by the appended claims.

What is claimed is:

1. A medication delivery pen comprising:
 - a body having opposing proximal and distal ends;
 - a dose control mechanism disposed in the proximal end of the body for setting
 - 5 and administering a dosage of medication;
 - a cartridge holder having a cartridge with a pierceably sealed distal end, an open proximal end removably attachable to the distal end of the body, and a plunger in sliding, fluid tight engagement within said cartridge;
 - a drive mechanism coupled between the dose control mechanism and the cartridge
 - 10 to exert an axial force on the plunger to inject the set dosage of medication, wherein the dose control mechanism triggers the drive mechanism to administer the injection of medication held in the cartridge; and
 - a mechanism that automatically disengages the drive mechanism from the dose control mechanism to permit the user to reset the dosage on the medication delivery pen.
 - 15
2. The medication delivery pen of claim 1 further comprising an automatic mechanism that allows the user to easily load a new cartridge and automatically reposition the drive mechanism on the plunger when the cartridge holder is mounted on the body of the medication delivery pen.
- 20
3. The medication delivery pen of claim 1 further comprising a magnifier on the body for viewing and setting of the desired dosage using the dose control mechanism.

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(72) Inventors; and

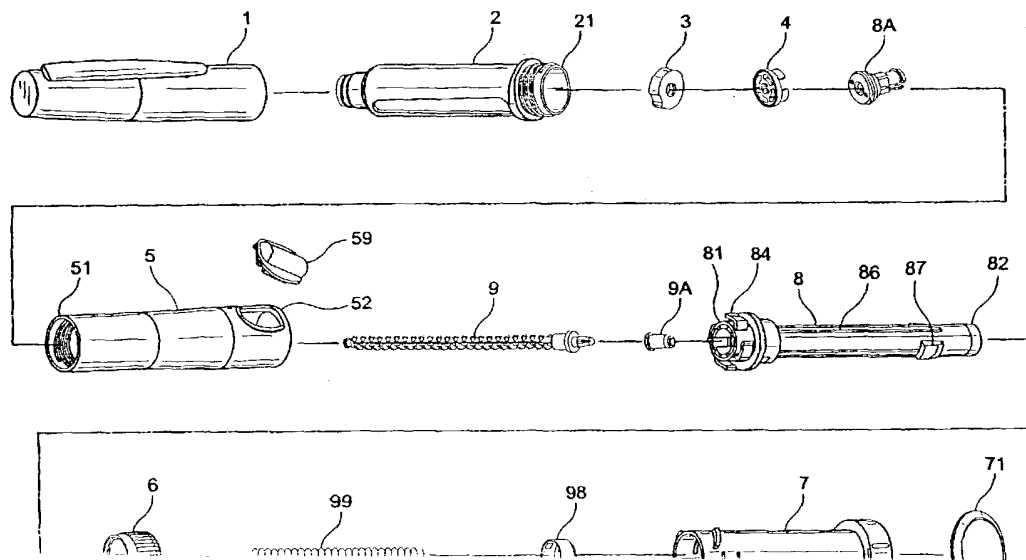
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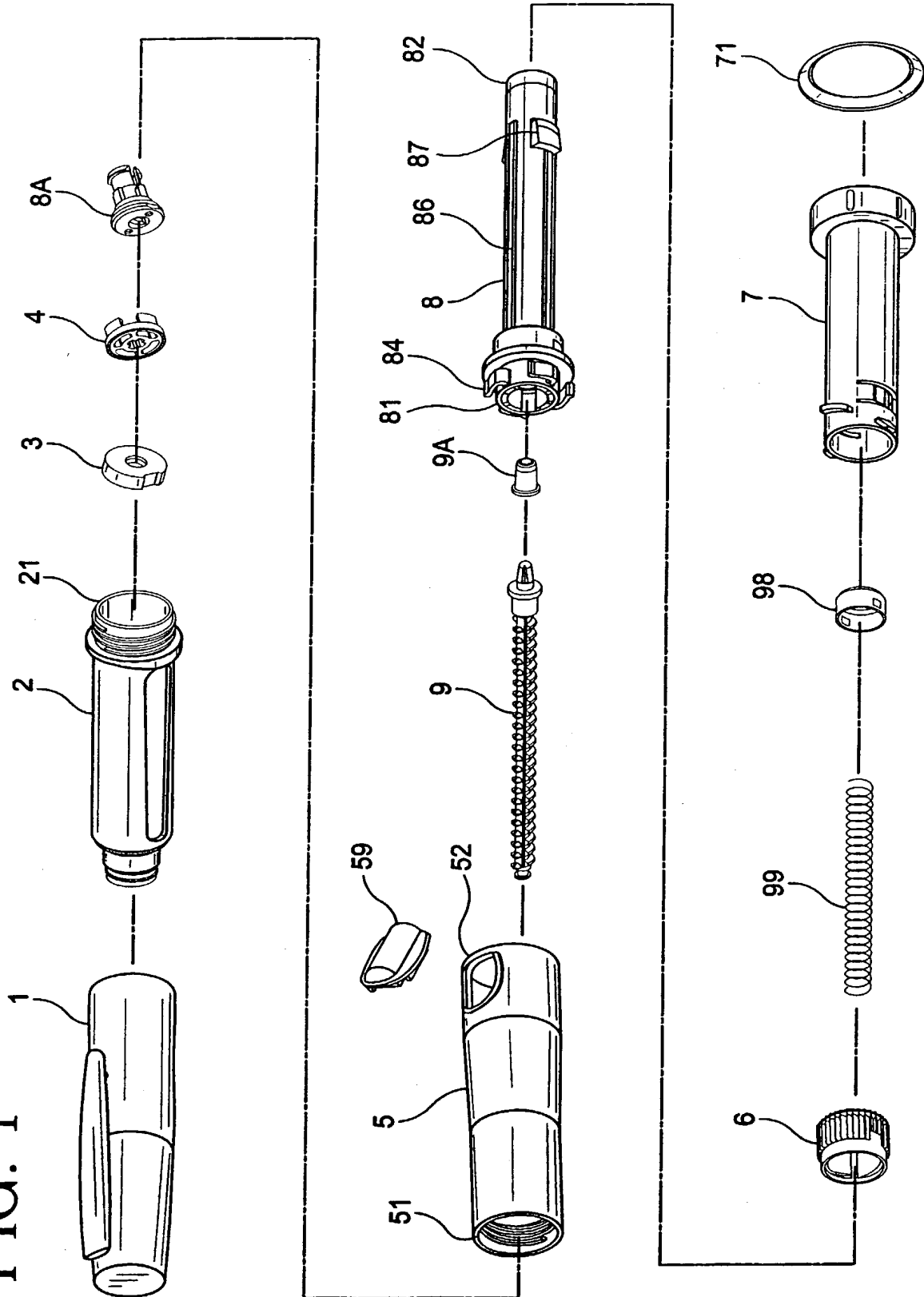


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the user to easily reset the dose on the medication delivery pen.

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FIG. 1



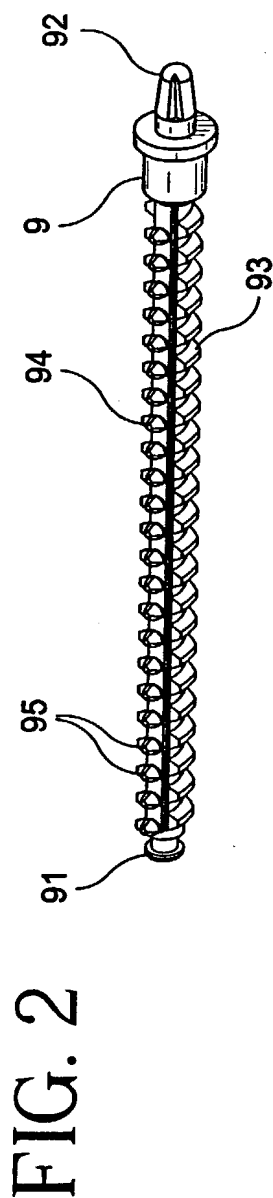


FIG-3

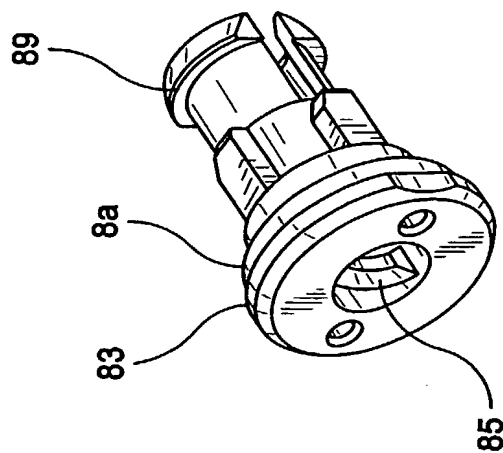


FIG-4

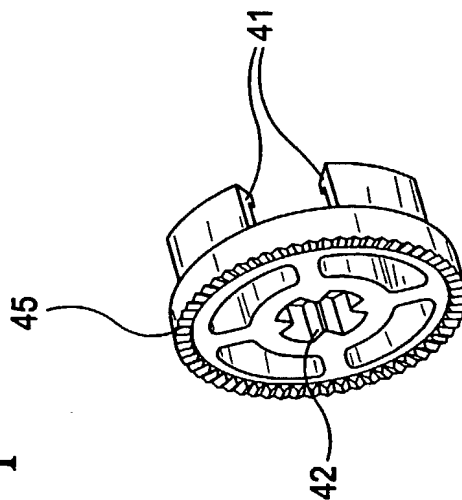


FIG. 5

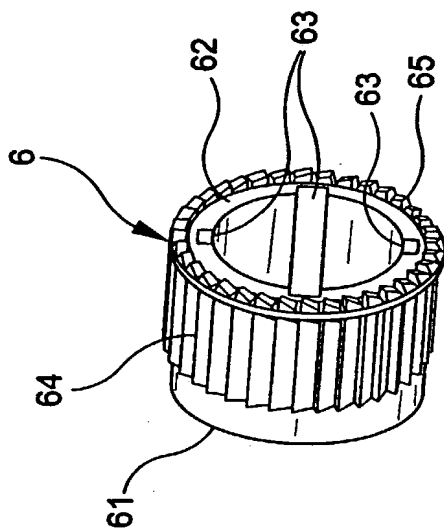
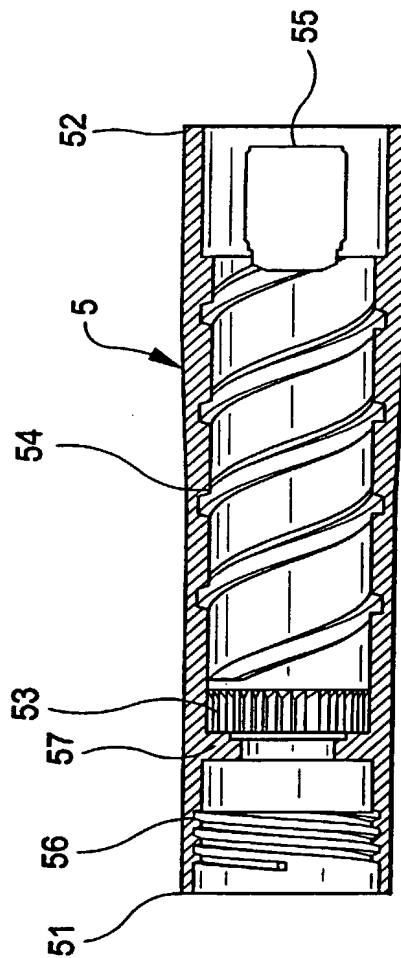


FIG. 6



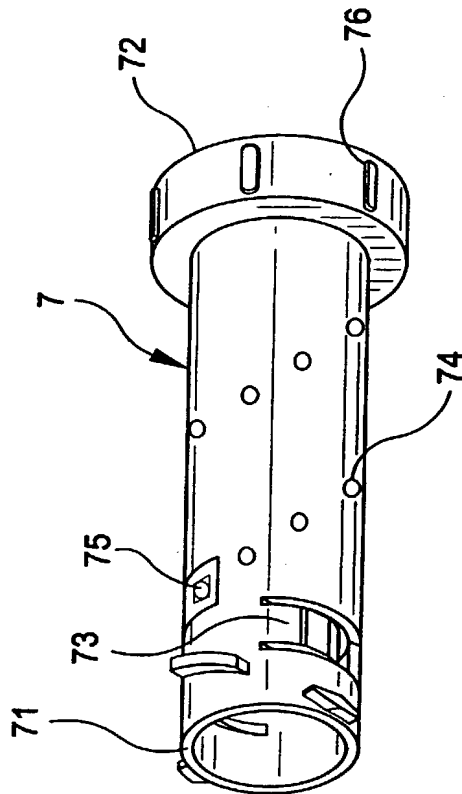


FIG. 7

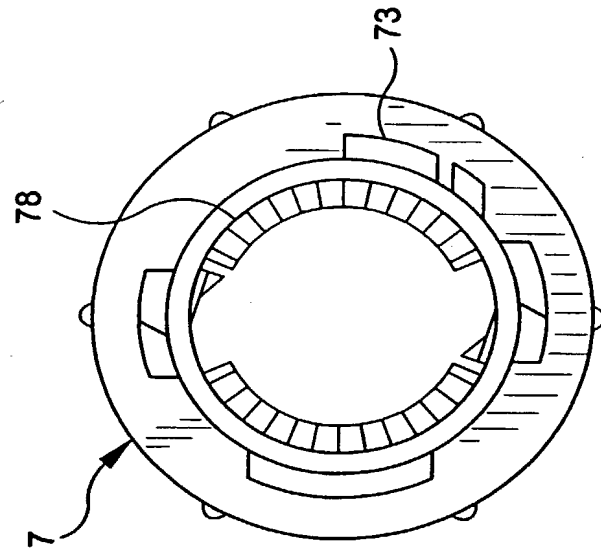
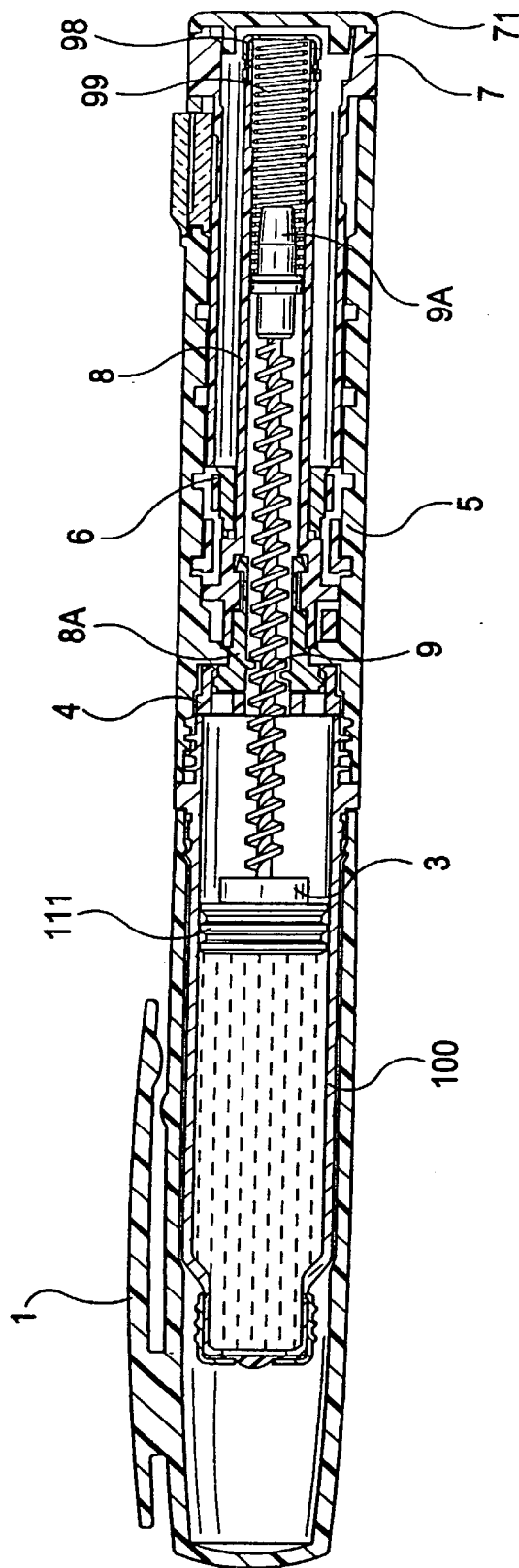
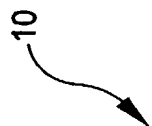


FIG. 8

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FIG-9



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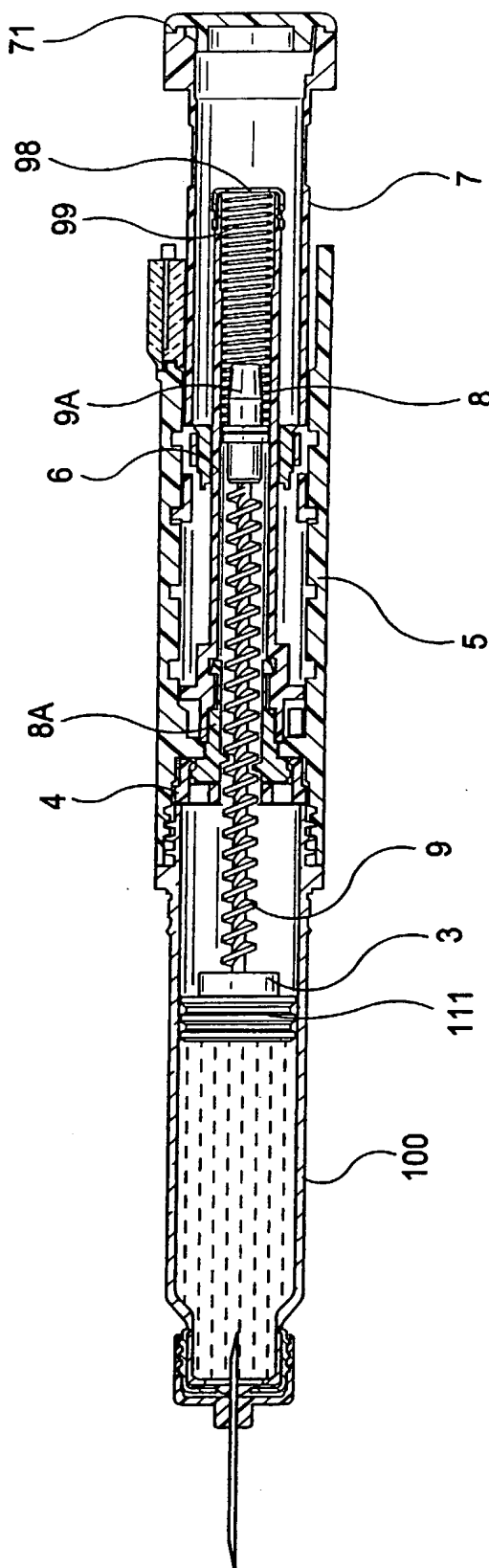


FIG-10

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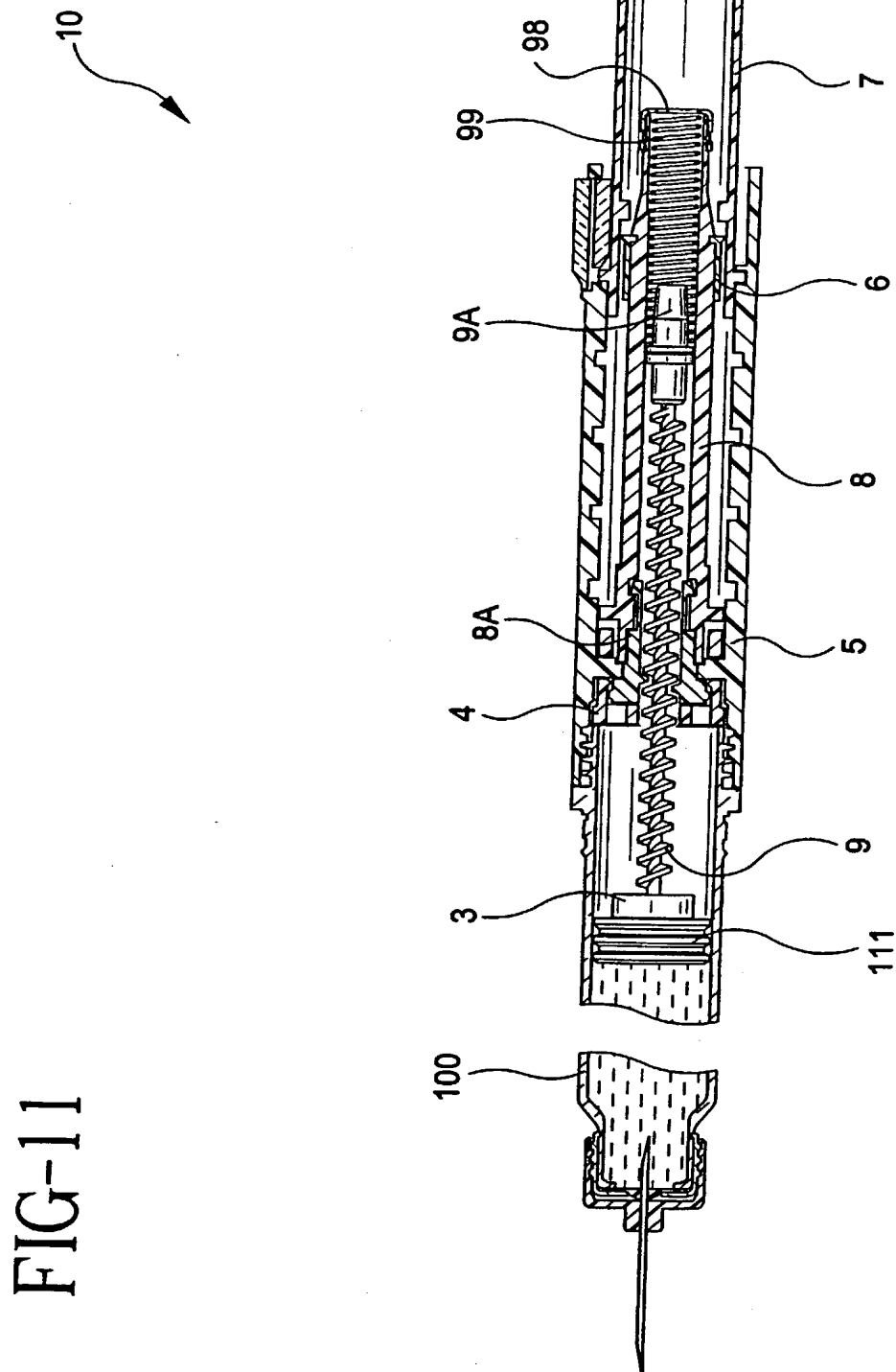
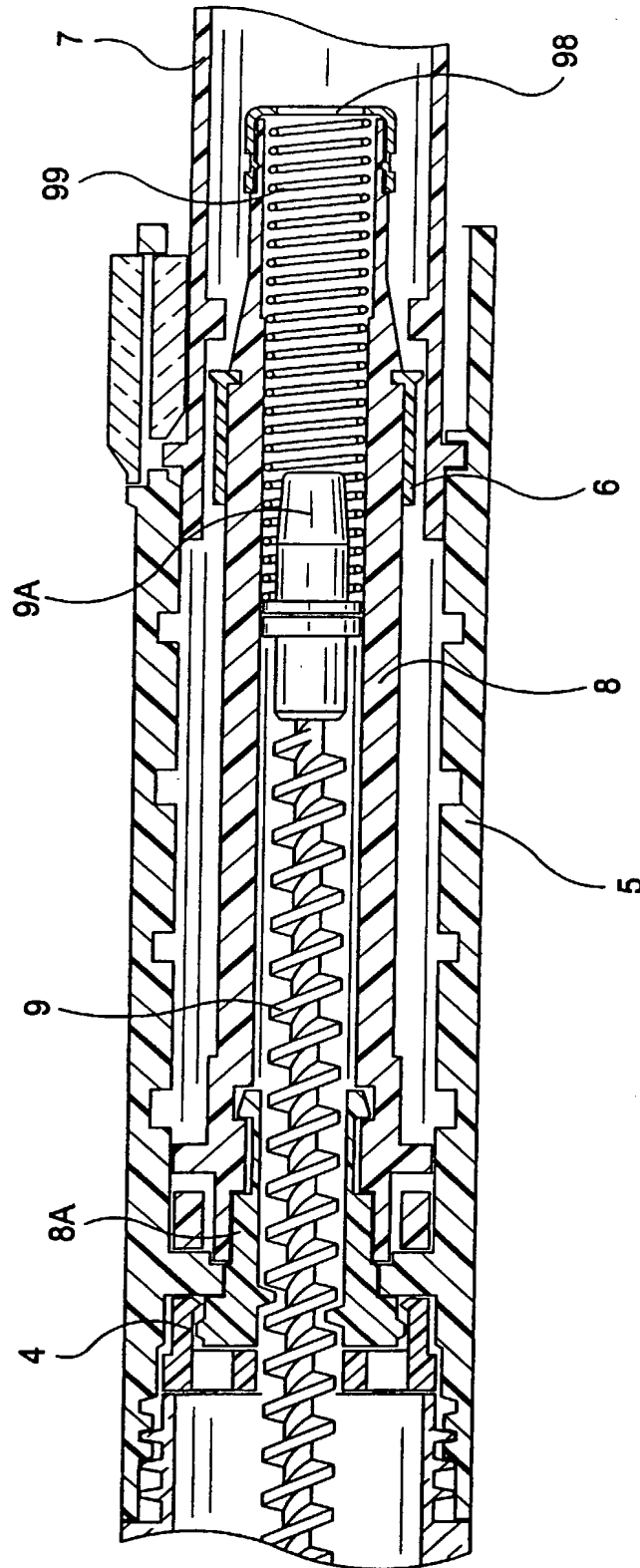
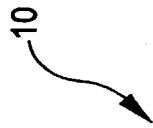


FIG-11

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FIG-12



DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled MEDICATION DELIVERY PEN, the specification of which is attached hereto unless the following box is checked:

Intl. Application #PCT/US00/20938
filed on: 7/31/2000

☒ was filed on August 5, 1999
Serial No. 60/147,330

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

NUMBER	COUNTRY	DATE FILED (Day/Month/Year)	PRIORITY CLAIMED	
			YES	NO

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional applications(s) listed below:

APPLICATION NUMBER	FILING DATE

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

APPLICATION SERIAL NO.	FILING DATE	STATUS (Patented, Pending, Abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

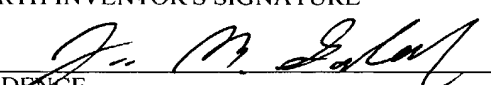
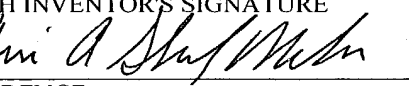
NAME	REG. NO.	NAME	REG. NO.	NAME	REG. NO.
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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3